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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,191	12/19/2000	Liang-Chang Dong	ARC 2556N1	7458

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EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	17

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/740,191	DONG ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communicati n appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the request for extension of time (3 months), the Request for Continued Examination (RCE) under Rule 1.114 and the Preliminary Amendment, all filed 03/03/03.

Claims 12-24 are pending. Claims 12-23 have been amended. Claims 12-24 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase, "*wherein the dosage form is configured to expel the self-emulsifying drug formulation from the capsule*" in independent claims 12 and 18 raises new matter issues, since the applicant has not provided any citations of support for the amended claim language.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 19 recite the limitation, "further comprising an expandable layer formed of an *osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose*.". The claims are indefinite since it is unclear whether the expandable layer must comprise all of the three components (hydrogel, solute and hydroxyalkylcellulose) or only one selected from the group. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong *et al.* (US Pat. No. 5, 324,280); (collectively, "Wong").

Wong disclose an osmotic system for delivering a beneficial formulation to an environment of use wherein the osmotic system comprises: (a) a capsule; (b) a dosage amount of a beneficial agent liquid formulation; (c) an osmagent composition; (d) a semi-permeable composition; (e) at least one orifice that communicates with the exterior and the lumen wherein the osmotic system is delivered at a controlled rate. The formulation contains osmoagents (solutes), osmopolymers (hydrogels), various emulsions, oils, immiscible liquids, emulsifiers and the like (see reference col. 7, line 25 through col. 9, line 67); (col. 12, line 48 through col. 13, line 22) and claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 16-18, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert *et al.* (US Pat. No. 6,458,373 B1; collectively, "Lambert").

Lambert discloses a self-emulsifying drug formulation system whereby the system is used for oral administration of water insoluble or poorly water-soluble drugs, wherein the oil phase with a surfactant and drug or drug mixture is encapsulated into soft or hard gelatin capsules (see reference column 3, lines 45-52); (col. 9, lines 36-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-15, 19-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US Pat. No. 6,458,373 B1; collectively, "Lambert") in view of Wong *et al.* (US Pat. No. 5,324,280; collectively, "Wong").

Lambert, as discussed above, teaches a self-emulsifying drug formulation system whereby the system is used for oral administration of water insoluble or poorly water-soluble drugs, wherein the oil phase with a surfactant and drug or drug mixture is encapsulated into soft or hard gelatin capsules (see reference column 3, lines 45-52); (col. 9, lines 36-55).

Lambert teaches that the composition includes alpha-tocopherol, a surfactant or mixtures of surfactants, with and without an aqueous phase, and a therapeutic agent, wherein the composition is in the form of a self-emulsifying drug delivery system. The pharmaceutical composition can be stabilized by various amphiphilic molecules, including anionic, nonionic, cationic, and zwitterionic surfactants (col. 3, lines 45-58).

The therapeutic agent can be any compound having natural or synthetic biological activity, is soluble in the oil phase, including peptides, non-peptides and nucleotides and lipid conjugates and prodrugs (col. 6, lines 49-55).

Lambert teaches that in the self-emulsifying formulation, the oil phase with a surfactant and drug or drug mixture is encapsulated into soft or hard gelatin capsules. Suitable solidification agents include high molecular weight polyethylene glycols and glycerides that can be added to allow filling of the formulation into a hard gelatin capsule at a high temperature. Semi-solid formulations are formed upon room temperature equilibration. Upon dissolution of the gelatin in the stomach and duodenum, the oil is released and forms a fine emulsion with droplets. The emulsion is then taken up in the intestine and released into the bloodstream (col. 9, lines 36-55).

The emulsion formulations comprise an array of surfactants and additives (col. 10, lines 5-27). The examples demonstrate various emulsion processes and their results (col. 10 through col. 23).

Lambert is deficient only in the sense that he does not explicitly teach an expandable layer formed of an osmotic hydrogel and does not teach the capsule characteristics (inner surface, outer surface, semi-permeable membrane).

Wong, as discussed above, teaches an osmotic system for delivering a beneficial agent formulation to an environment of use, wherein the osmotic system comprises hydrogels, also known as osmopolymers, and also teaches an inner capsule wall, an outer capsule wall and a semipermeable wall or membrane (see reference column 3, line 45 through col. 4, line 13); (col.8, line 48 through col. 9, line 25).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Wong within the teachings of Lambert because Wong explicitly teaches a drug delivery system comprising a capsule that contains the liquid drug formulation and various hydrogels, which serve to provide imbibition properties and swell in water and biological fluids and Lambert teaches a self-emulsification drug delivery system wherein the drug or drug mixture is encapsulated and filled into capsules. The expected result would be an improved and highly effective self-emulsification system for the delivery of therapeutic agents.

Prior Art made of record and deemed relevant by the Examiner:

Rudnic *et al.* US Pat. No. 5,897,876 (04/1999)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703)

308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
March 14, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600